UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,102	05/01/2001	Dennis A. Carson	220002062900	5759

7590 08/04/2003

Kevin L. Bastian, Esq.
Townsend and Townsend Crew LLP
Two Embarcadero Center, Eitht Floor
San Francisco, CA 94111-3834

EXAMINER
YU, MISOOK

ART UNIT	PAPER NUMBER
1642	21

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/847,102	CARSON ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears n the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,16,22 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,16,22 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence alignment* .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group V, antibody to SEQ ID NO:68 and pharmaceutical comprising antibody to SEQ ID NO:68 in Paper No. 20 is acknowledged. The traversal is on the ground(s) that groups I-X drawn to antibody to frizzled receptors 1-10 are embodiments within the breadth and scope of the definition of an antibody and examination of the groups would not put undue burden on the examiner. This is not found persuasive because the receptors 1-10 have different products as evidenced by the different SEQ ID NOs, therefore antibodies binding to the different products are also different products and searching 10 patentably different products would put undue burden on the examiner. Claims 1-9, 16, 22, and 27 are pending and examined on merits.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "antibody specifically binds to the frizzled 5 receptor" but it is not clear what the metes and bound are for the limitation in light of claim 9 which says antibody of claim 1 also binds to "a frizzled-2 receptor". Are "a frizzled 5 receptor" in

claim 1 and "a frizzled-2 receptor" same proteins? If same, why use two different names?

Claim 4 recites "capable of sensitizing malignant cells expressing the frizzled 5 receptor to a cytotoxic factor" but it is not clear what the limitation means.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 16, 22, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are interpreted as drawn to antibody to a genus of protein called a frizzled 5 receptor. The specification provides evidence for one species. Based on one species, one cannot predict the types of additional species such one resulting from allelic and/or splicing variants. Since the genus includes a large number of unpredictable species, possession of only one species is not seen as sufficient to reasonably convey possession of the entire genus. It is concluded that applicants adequately describes SEQ ID NO:68.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention. The claim is interpreted as drawn to antibody capable of inhibiting binding of a genus of Wnt ligand to frizzled 5 receptor. The instant specification does not disclose any new ligand to the receptor. He et al (IDS # 93, 1997, Science vol. 275, pages 1652-4) teach only one ligand, i.e. Wnt-5A for the receptor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 16, 22, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Tanaka et al (IDS, #1711998, Proc. Natl. Acad. Sci. USA. vol. 95, pages 10164-9), He et al (IDS # 93, 1997, Science vol. 275, pages 1652-4), or Wang et al (IDS #184, 1996, J. Biol. Chem. vol. 271, pages 4468-76) in view of Campbell, A. (1986, Monoclonal antibody technology, chapter 1 only, Elsevier Science Publishers B.V., Netherlands).

The claims are interpreted as drawn to antibody by itself, or label attached, or cytoxic agent attached, capable of binding to instant SEQ ID NO:68 for therapeutic and diagnostic uses. Any one of Tanaka et al, He et al, or Wang et al teach instant SEQ ID NO:68. See the attached sequence alignment. Instant claim 1 says that "the frizzled 5 receptor expressed on the malignant cell" but the instant SEQ ID NO:68 and the N-terminal 1-235 amino acids of the protein taught by the prior art are same and the

specification does not teach frizzled 5 receptor expressed on the malignant cells is different from the N-terminal part of the protein. It is the Office's position that an antibody capable of binding to the N-terminal 1-235 amino acids of the protein taught by the prior art is also capable of binding to the extracellular domain of the frizzled 5 receptor expressed on the malignant cell. The primary references does not teach any antibody. However, Campbell, A. teaches that making monoclonal and polyclonal antibodies is a routine matter (see Table 1.1 at page 5) and one of ordinary skill in the art is motivated to make antibody for various reasons (see the last paragraph of page 29). Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make an antibody and/or monoclonal antibody capable of binding to the instant SEQ ID NO:68 using an epitope from the primary references. As for claim 5, He et al teach Wnt-5A is the ligand for the receptor, therefore blocking the receptor with antibody capable of binding to said receptor will inhibit binding of said ligand to the receptor. As for claims 6 (labeled antibody), claim 7 (human antibody), Campbell, A teaches attaching label to antibody and human antibody is known in the art before the effective filing date of the instant application. See page 19.

Further, the Board of Patent Appeals and interferences has taken the position that once an antigen has been isolated, the manufacture of antibodies against it is *prima facie* obvious. See Ex parte Erlich 22 USPQ2d 1463 (BdPatApp&Int 1992).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
July 24, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600
1600